Appl. No. 09/691,405
Amdt. dated October 18, 2005
Reply to Office Action of May 12, 2004

PATENT

REMARKS/ARGUMENTS

Claims 1-2, 5-10 and 12-20 are pending. Claims 19 and 20 have been amended.

The purpose of the amendments made herein is to remove issues for appeal and to place the claims in better condition for appeal.

Claims 19 and 20 were rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement. In particular, it was alleged that the concept of "determined simultaneously" and "substantially simultaneously" are not supported. Although applicants respectfully disagree, to remove issues for appeal, applicants have amended claim 19 to recite "wherein the data values obtained for the test data set are determined in an automated test system." Thus, claim 19 only recites that the test data set has values that are obtained in an automated test system. Similarly, claim 20 only recites that the set of one or more tests are preferred in an automated test system. Accordingly, withdrawal of these rejections to claims 19 and 20 is respectfully requested.

The pending claims were also rejected under 35 USC §112, first paragraph, as not being enabled. This rejection is respectfully traversed for at least the following reasons.

The Examiner continues to argue that the specification "does not associate any antigen (or antibody) with any particular disease with respect to presence (or absence) and amounts." It is also argued that the specification "does not disclose how discrimination between different autoimmune diseases, particularly those that involve overlapping autoantibodies, is to be implemented." Further it is argued that "the underlying method and intent of the claims is a data mining method to discover those antibodies, if any, that may be statistically associated with the named autoimmune diseases and be capable of discriminating against them." It is respectfully submitted that the present invention neither involves nor claims either the association of particular antigens or antibodies with particular diseases or the determination or discovery of unknown antibodies related to particular diseases.

The present invention is not concerned with associating particular antibodies with diseases. Rather, the invention is concerned with correlating, using a KNN process, between a test data set and a plurality of reference data sets and providing a statistically derived decision as to whether the test data set is associated with one or more of the diseases with which the

reference data sets are known to be associated. The present invention provides an aid for diagnosis; it does not provide a data mining method for discovering autoantibodies that may be associated with a specific autoimmune disease. The present invention is concerned with discovering similarities between references data sets and a test data set. That is, the invention resides in, and claim 1, for example, expressly recites, comparing the test data set and the reference data sets which include reference data sets obtained for each of the one or more systemic autoimmune diseases by subjecting biological samples of reference subjects, each known to have one of the one or more systemic autoimmune diseases, to said set of one or more tests, and reference data sets obtained by subjecting biological samples of reference subjects known to not have one of the one or more systemic autoimmune diseases to said set of one or more tests. As taught at page 5, lines 1 to 5, for example, the test data set is based on samples subjected to the same tests as the reference sample. And this is reflected in the claims wherein it is recited that the reference data sets are each obtained by subjecting a sample of a reference subject "to said set of one or more tests," (emphasis added) with said set of tests referring to the set of tests applied to the sample of the test subject. There is therefore no correlation between antibodies and diseases, only between one test data set and a plurality of reference data sets and the diseases with which they are associated.

The present invention is also is also not directed to making a determination of or discovering unknown antibodies; whichever antibody tests are decided to be used are used for both the reference data sets and the test data set. It is irrelevant for the purposes of the claimed invention what antibody tests, and therefore also which antibodies, are used for the tests, so long as there is some amount of consistency in the tests that are applied to both the reference samples and the test sample to derive the data sets. The use of particular antibodies and particular antibody tests may lead to improved results (see, e.g., page 8, lines 9-12), however, the invention and the pending independent claims are not limited to the use of particular antibodies or antibody tests. Nor is the use of specific antibodies and antibody tests necessary as any antibodies and antibody tests known to one skilled in the art may be used. For example, as antibodies are discovered, the tests to identify such antibodies could be used on the reference samples and the test sample to add an extra dimension to the N-dimensional data being processed according to

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the present invention. It is routine to one skilled in the art of antibody discovery to discover new antibodies as well as new techniques for such discovery.

As the invention is intended as an aid to diagnosis, a certain amount of discrimination between the various autoimmune diseases is achieved by the KNN process as described at the paragraph beginning on page 5, line 14. For example, the disease that is associated with the k nearest (reference) data points is that which is identified as being present in the test sample, and if more than one disease is associated with the k nearest (reference) data points then the diagnosis is for each of the diseases (or none if the reference data points are associated with reference samples known to be disease free). That is, the KNN process itself provides discrimination by identifying the one or more (or none) of the diseases that are associated with the k nearest reference data points. Additional refinements are also presented in the cited paragraph, such as, for example, to determine a confidence level of the diagnosis. Again, it is not particularly relevant what the antibodies are, just that each of the data sets have been subjected to the same antibody testing so that a correlation can be made using the KNN process

Accordingly, it is respectfully asserted that the present specification provides sufficient guidance to enable one skilled in the art to implement the claimed invention. Again, the presently claimed invention is directed to a method of processing the data as recited therein. There is no recitation in the claims of discovering antibodies or of associating antibodies with particular diseases. Furthermore, the specification is not a mere "invitation to experiment" as it is characterized in the Office Action. The specification is a teaching that when combined with the existing knowledge and the routine level of skill among data processors and statisticians provides a fully enabling disclosure to support the claims. To the extent one skilled in the art would need to make assumptions as to what specific data would be used, such basic assumptions are a routine matter for one skilled in the art. For example, one skilled in the art would easily be able to implement data filtering, skew adjustment and normalization techniques as may be desired without undue experimentation.

Accordingly, the rejection of the claims under 35 USC §112, first paragraph, is respectfully traversed.

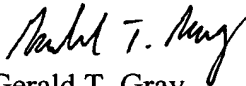## CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

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